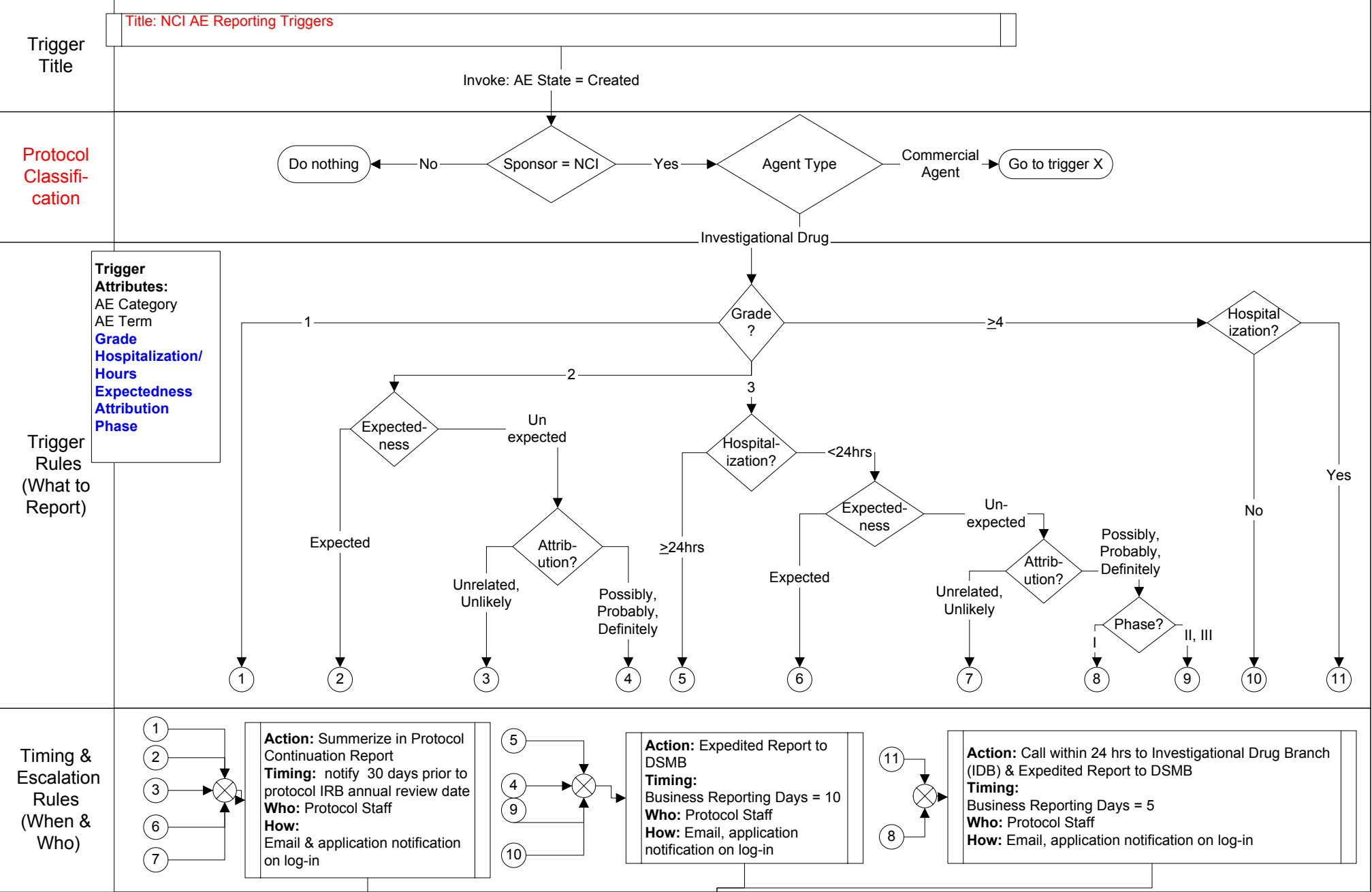


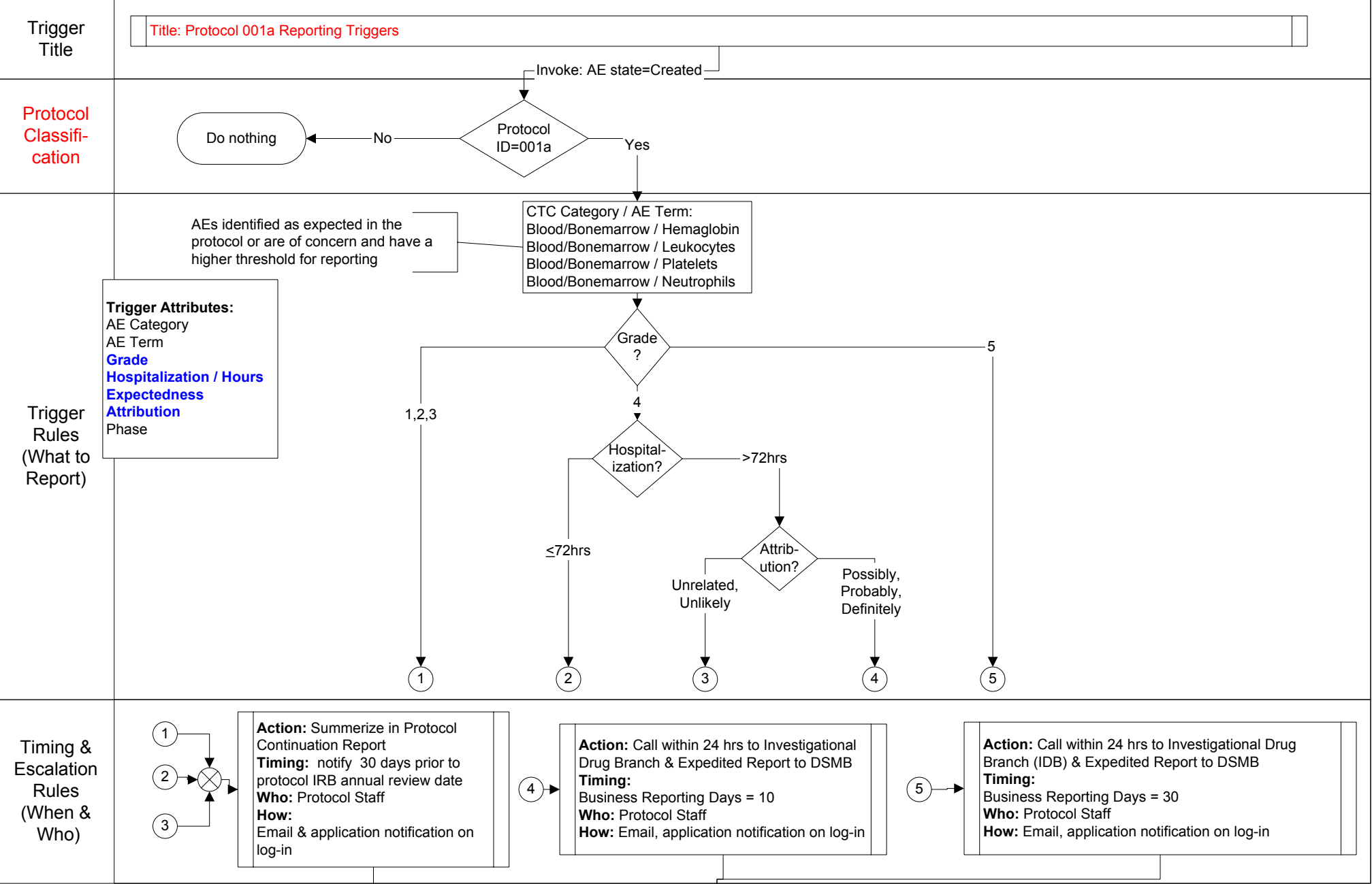
Sponsor Level Trigger Concept: These rules are specific to a Sponsor & would usually apply to a classification of protocols specific for that sponsor (RP20)

Sponsor Level Example - NCI



Protocol Level Trigger Concept: These rules only apply to a specific protocol (RP21)

Protocol Level Example - 001a



**Example for a 10 day report period**RF17  
B

RP19

**Notification Timing & Escalation Rules**

Day	Escalation Rule	Role to Notify	Mechanism	Message
1	N/A	CRA	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
3	Data not completed	CRA	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
5	Data not completed	PI	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
9	Data not completed	PI	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
15	Data completed	PI	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE report submitted on [date]. AE needs follow-up. [Notice #].